CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
vs.	§	
	§	
APOTHECURE, INC.,	§	DALLAS COUNTY
SPECTRA PHARM, INC.,	§	
and GARY D. OSBORN, individually,	§	
	§	
Defendants.	§	____ JUDICIAL DISTRICT

FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION

Plaintiff, the STATE OF TEXAS, acting by and through Attorney General Greg Abbott ("State"), and Defendants, APOTHECURE, INC., SPECTRA PHARM, INC., and GARY DOUGLAS OSBORN, individually ("Defendants"), having consented to the entry of this Final Judgment and Agreed Permanent Injunction ("Judgment") have jointly moved that the Court enter this Judgment.

The Court, after considering the agreement of the parties, the parties' stipulations, the pleadings, and the supporting authorities, is of the opinion that said agreement should be in all things approved. Accordingly, the Court hereby enters and renders this Final Judgment and Agreed Permanent Injunction.

I. STIPULATIONS

1. The parties, by the duly authorized representatives' signatures, stipulate as follows:

A. They understand and agree to the terms of this Judgment.

B. They actively participated in the negotiations leading up to this Judgment and are aware of the duties placed upon them by it and are desirous and capable of carrying out those duties in full.

C. This Court has jurisdiction, through the Deceptive Trade Practices – Consumer Protection Act, TEX. BUS. & COM. CODE §17.41 *et seq.* ("DTPA") and the Texas Food, Drug and Cosmetic Act and ("TDFCA"), TEX. HEALTH & SAFETY CODE §431.001 *et seq*., over the subject matter and over all parties to this action;

D. Venue of this matter is proper in Dallas County by virtue of the fact that this lawsuit arises out of Defendants' business in Texas.

E. The Civil Penalties awarded to the State of Texas constitute claims to, and for the benefit of, a governmental unit, as defined under 11 U.S.C. §101(27), and are not compensation for actual pecuniary loss and would be a debt that would be nondischargeable in a subsequently filed bankruptcy proceeding under either Chapter 7 or Chapter 11 and that, in the event a voluntary or involuntary chapter 7 or chapter 11 bankruptcy proceeding is commenced against debtors, the debtors stipulate that they shall not contest either directly or indirectly future attempts, if any, by the State of Texas to have such debt declared nondischargebable in accordance with 11 U.S.C. §523(a)(7).

F. Plaintiff's action against the Defendants, including the entry and enforcement of this Judgment, is exempted pursuant to 11 U.S.C. §362(b)(4) from the automatic

stay of 11 U.S.C. §362(a).

G. The parties have waived all rights of appeal from this Judgment.

H. The terms of this Judgment are sufficiently detailed and specific to be enforceable by the Court in conformance with Tex. R. Civ. P. 683.

I. Defendants have full and actual notice of the terms of this Judgment;

J. Defendants have received copies of this Judgment, and the issuance and service of a writ of injunction is waived by Defendants.

K. The Court shall have continuing jurisdiction to enforce this Judgment.

L. This Judgment represents a compromise and settlement of all matters arising out of facts alleged by the State of Texas in this cause under the TFDCA and the DTPA.

II. DEFINITIONS

2. For purposes of this Agreed Final Judgment and Permanent Injunction, the following definitions shall apply:

A. "Adulterated drug" means a drug that meets one or more of the criteria in §431.111 of the Texas Food, Drug, and Cosmetic Act.

B. "Advertising" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics.

C. "Bulk drug substance" means a bulk drug substance that is an active ingredient in the compounded drug.

D. "Competent and reliable scientific evidence" means tests, analysis, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons

qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

E. "Compound" or "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug by a licensed pharmacist that is done within the practice of pharmacy and pursuant to a prescription or initiative from a practitioner for a identified individual patient or based upon a history of receiving prescription orders for the drug products within an established pharmacist-practitioner-patient relationship.

F. "Defendants" means APOTHECURE, INC., SPECTRA PHARM, INC., and GARY DOUGLAS OSBORN, individually, and includes their officers, agents, servants, employees, successors and assigns as well as any other persons acting on any of their behalf who receive actual notice of this Final Judgment and Agreed Permanent Injunction by personal service or otherwise.

G. "Drug" means articles recognized in the official United States Pharmacopoeia National Formulary, or any supplement to it, articles designed or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, articles, other than food, intended to affect the structure or any function of the body of man or other animals, and articles intended for use as a component of any article specified in this subdivision. The term does not include devices or their components, parts, or accessories. A food for which a claim is made in accordance with Section 403(r) of the federal Food, Drug and Cosmetic Act, and for which the claim is approved by the Secretary of Health and Human Services, is not a drug solely because the label or labeling contains such a claim.

H. "False advertising" of a drug, or other regulated articles, means advertising that is false, deceptive, or misleading in any particular.

I. "FDA" means the U.S. Food and Drug Administration.

J. "FFDCA" means the Federal Food, Drug, and Cosmetic Act.

K. "Food" is defined in §431.002 (16) of the Texas Food, Drug, and Cosmetic Act and means articles used for food or drink for man, including dietary supplements, chewing gum, and articles used as components of any such article.

L. "Good manufacturing practices" or "GMPs" means the current manufacturing practices for drugs or foods as identified in 25 T.A.C. §§ 229.212, 229.242, 229.251, 229.420, 229.429, including but not limited to 21 CFR PART 110

("Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food") as amended, 21 CFR 111 ("Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements ") as amended, 21 CFR, Part 210 ("Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs") as amended, 21 CFR, Part 211 ("Current Good Manufacturing Practice for Finished Pharmaceuticals") as amended, 21 CFR, Part 216 ("Pharmacy Compounding") as amended, 21 CFR, Part 225 ("Current Good Manufacturing Practice for Medicated Feeds") as amended, and 21 CFR, Part 226, ("Current Good Manufacturing Practice for Type A Medicated Articles") as amended.

M. "Introduce or deliver for introduction into commerce" means the sale, receipt, offer for sale, delivery, holding, giving away of a drug, device, or food, including a dietary supplement;

N. "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of the Texas Food, Drug, and Cosmetic Act that any word, statement, or other information that appears on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of the article, or is easily legible through the outside container or wrapper.

O. "Labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

P. "Manufacture" means the process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing, or quality control of a drug or drug product, but does not include compounding that is done within the practice of pharmacy and pursuant to a prescription or initiative from a practitioner for an identified individual patient.

Q. "Misbranded drug" means a drug that meets one or more of the criteria in §431.112 of the Texas Food, Drug, and Cosmetic Act.

R. "Misbranded food" means a food, including a dietary supplement, that meets one or more of the criteria in §431.082 of the Texas Food, Drug, and Cosmetic Act.

S. "New drug" means: (A) any drug, except a new animal drug, the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of

drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof (except that such an unrecognized drug is not a "new drug" if at any time before May 26, 1985, it was subject to the Food and Drug Act of June 30, 1906, and if at that time its labeling contained the same representations concerning the conditions of its use); or (B) any drug, except a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

T. "Prescription" means an order from a licensed practitioner; or an agent of the practitioner designated in writing as authorized to communicate prescriptions to a pharmacist for a drug to be dispensed for a specific, individual patient.

U. "Texas Food, Drug and Cosmetic Act" and "TFDCA" mean TEX. HEALTH & SAFETY CODE § 431.001 *et seq*.

V. "Texas Deceptive Trade Practices - Consumer Protection Act" and "DTPA" mean TEX. BUS. & COM. CODE ANN. § 17.41 *et seq*. ("DTPA").

W. "TDSHS" means the Texas Department of State Health Services.

X. "USP/NF" means the current edition of the United States Pharmacopeia/National Formulary.

Y. "Wholesale distribution" means distribution of prescription drugs to a person other than a consumer or patient as defined in §431.401(11) of the Texas Food, Drug, and Cosmetic Act and in compliance with §431.401-415.

III. FINDINGS

IT IS THEREFORE ORDERED, ADJUDGED and DECREED THAT:

3. The Court, after being fully advised in this matter and after considering the agreement of the parties, the parties' stipulations, and the pleadings, finds as follows:

A. The settlement of the parties, in the substance and form of this Judgment, is fair, reasonable, just, and in the best interest of the parties and the public and

B. A permanent injunction should be issued as granted in this Judgment, and that Plaintiff is entitled to recover monetary relief from Defendants as set forth herein.

IV. INJUNCTION

4. **IT IS FURTHER ORDERED THAT** GARY DOUGLAS OSBORN, APOTHECURE, INC., and SPECTRA PHARM, INC., including their officers, agents, servants, employees, and any other persons in active concert or participation with any of the Defendants, who receive actual notice of this order by personal service or otherwise, whether acting directly or through any trust, corporation, subsidiary, division, or other devise shall not:

A. Compound an unapproved new drug pursuant to §431.114 of the TFDCA or an adulterated drug pursuant to §431.111 of the TFDCA or a misbranded drug pursuant to §431.112 of the TFDCA by using a bulk drug substance that 1) is not a bulk drug substance that is in an FDA-approved drug or 2) fails to comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists;

B. Compound an unapproved new drug pursuant to §431.114 of the TFDCA or an adulterated drug pursuant to §431.111 of the TFDCA before receiving a prescription order for an individually identified patient from a practitioner or without a history of receiving prescription orders for the drug products within an established pharmacist-practitioner-patient relationship;

C. Compound an unapproved new drug pursuant to §431.114 of the TFDCA or an adulterated drug pursuant to §431.111 of the TFDCA by using a bulk drug substance that is not manufactured in a facility registered under section 510 of the FFDCA;

D. Compound an unapproved new drug pursuant to §431.114 of the TFDCA or an adulterated drug pursuant to §431.111 of the TFDCA by using bulk drug substances that fail to have valid certificates of analysis;

E. Compound an unapproved new drug pursuant to §431.114 of the TFDCA or an adulterated drug pursuant to §431.111 of the TFDCA by using bulk drug substances that only have valid certificates of analysis and fail to meet the other

requirements of this Judgment;

F. Compound an unapproved new drug pursuant to §431.114 of the TFDCA, an adulterated drug pursuant to §431.111 of the TFDCA, or a misbranded drug pursuant to §431.112 of the TFDCA by using ingredients, other than bulk drug substances, that fail to comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists;

G. Compound a drug for injection that uses ingredients that are labeled or designated in the USP/NF as not for use in injections, including but not limited to USP Water for Irrigation and Sodium Chloride for Irrigation Solution;

H. Compound a drug which appears on an FDA list as a drug which has been withdrawn from the marketplace because the drug or its components have been found to be unsafe or ineffective, including but not limited to Colchicine injections, Cobalt Chloride, and Adrenal Cortex;

I. Compound a drug product if it has been identified by the FDA in a regulation as a drug product which is difficult to compound without affecting the safety or effectiveness of the product;

J. Compound any drug incorporating DMPS or any bulk drug substance that is not in an FDA-approved drug or in the USP/NF monograph, unless FDA includes the bulk drug substance in a final list of drugs that can be compounded under 21 U.S.C. §353a (b)(1)(A)(i)(III);

K. Compound any drugs for wholesale distribution in violation of §431.401-415 of the TFDCA;

L. Distribute manufactured drugs 1) without a wholesale distributor's license issued by the TDSHS or 2) to an entity or person that is not authorized to possess prescription drugs;

M. Sell, deliver, advertise, offer for sale, hold for sale, or give away any drug unless the drug has been approved by the FDA or is otherwise exempted by compliance with an over-the-counter federal monograph or the drug is compounded in compliance with terms 4. A-L above;

N. Introduce into commerce an adulterated or misbranded drug;

O. Introduce into commerce any over-the-counter drug that does not comply with the

over-the-counter federal monograph for such drug, including but not limited to a drug whose label lacks a drug facts panel and a drug that lacks tamper resistant packaging;

P. Disseminate any marketing materials, instructions, or protocols for a product incorporating Adrenal Cortex as a component or packaging a product incorporating Adrenal Cortex as a component in a manner to subvert the federal prohibition of Adrenal Cortex in a drug product;

Q. Advertise or represent that a drug approved by FDA is effective for treating diseases of the body, when the FDA has not approved the drug for the specific advertised use;

R. Advertise or make representations for a drug compounded by Defendants unless the advertisement or representation promotes the drug (i) only for the intended uses that were the basis for FDA approval of a drug containing the bulk drug substances in the compounded drug or (ii) in compliance with the designated use in the standards for bulk drug substances in the applicable USP;

S. Make any express or implied claim in the labeling, marketing, or advertising of a dietary supplement that the dietary supplement may be used in the diagnosis, cure, mitigation, treatment or prevention of disease in humans;

T. Use testimonials to make claims about a drug or food that Defendants cannot lawfully make themselves;

U. Make any express or implied a) structure/function claims or b) health benefit, performance, efficacy or safety claims in the labeling or marketing of a food marketed as a dietary supplement, unless at the time the claim is made, competent and reliable scientific evidence exists substantiating such claim, and the claim does not make the product a drug;

V. Introduce into commerce an adulterated or misbranded food;

W. Introduce into commerce a food, including a dietary supplement, whose label fails to prominently display, in such a manner to render it likely to be read and understood by the ordinary individual under customary conditions, information and statements required by regulations; and

X. Manufacture foods within this state, including but not limited to placing the name and address of any business owned by a Defendant on the labeling, unless

Defendant complies with the current good manufacturing practices and is appropriately licensed by TDSHS.

5. **IT IS FURTHER ORDERED THAT** Defendants shall develop and implement a plan for monitoring and regulating all of Defendants' Internet sites, including all internet search parameters, such as metatags, search and source codes, and all advertising and promotional materials for all dietary supplements advertised or offered for sale to insure that they do not include claims that said foods treat, cure, mitigate, or prevent diseases and serious illnesses. Defendants shall also develop and implement a plan for the monitoring and regulation of all of Defendants' Internet sites, including all internet search parameters, such as metatags, search and source codes, and all advertising and promotional materials for all drugs to insure that these sites or materials do not include claims that promote unapproved drugs, FDA-approved drugs for unapproved uses, or drugs compounded without compliance with paragraph 4. A and C-L above.

6. **IT IS FURTHER ORDERED THAT** if any Defendant compounds drugs, potency and identity testing must be conducted on all drugs compounded.

7. **IT IS FURTHER ORDERED THAT** Defendants must compile and maintain records for all drugs compounded by Defendants, electronically or manually, that show compliance with the terms in paragraph 4. A-L above and make these records available for inspecting and copying by TDSHS within 5 business days, if requested by an authorized agent of the TDSHS. If Defendants maintain the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this section, either on site or within 5 business days, constitutes prima facie evidence of failure to keep and

maintain records in violation of this Final Judgment and Agreed Permanent Injunction.

8. **IT IS FURTHER ORDERED THAT** Defendants shall permit TDSHS to conduct an inspection of all aspects of Defendants' facilities to determine whether Defendants are in compliance with the TFDCA and the terms of this Final Judgment and Agreed Permanent Injunction and to cooperate with TDSHS inspectors during said inspection, including but not limited to permitting access to or copying of any record as authorized by §§ 431.042 through 431.044 of the TFDCA or as ordered in this Judgment.

9. **IT IS FURTHER ORDERED THAT** Defendants APOTHECURE, INC., and GARY DOUGLAS OSBORN shall destroy all products that were compounded by Defendants without complying with all of the requirements of the terms in paragraph 4. A and C-L above. Defendants can dispense drugs that violate only 4. B above, and not 4. A and C-L, that have already been compounded prior to November 16, 2012 (lack of prescription order for a specific patient prior to compounding). The destruction of drugs that violate 4. A and C-L shall be witnessed by an authorized agent of the TDSHS.

V. MONETARY PAYMENT

10. **IT IS FURTHER ORDERED THAT** Defendants, APOTHECURE, INC., SPECTRA PHARM, INC., and GARY DOUGLAS OSBORN, individually, pay and deliver One Hundred Thousand Dollars ($100,000.00) to the Office of the Attorney General as civil penalties pursuant to §431.0585 of the TFDCA and §17.47(c)(1)(A) of the DTPA. **THIS ORDER** shall further constitute a judicial determination that these civil penalties shall constitute a civil fine or penalty to and for a governmental unit and are not compensation for actual pecuniary loss.

11. **IT IS FURTHER ORDERED THAT** Defendants shall pay Forty Thousand Dollars ($40,000.00) to the Office of the Attorney General as attorneys fees and investigative costs under §431.047 of the TFDCA and the TEX. GOVT. CODE §402.006(c).

12. **IT IS FURTHER ORDERED THAT** the Texas Department of State Health Services shall have and recover the sum of Sixty Thousand Dollars ($60,000.00) from Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY DOUGLAS OSBORN, individually, as the reasonable expenses incurred by the Texas Department of State Health Services in obtaining injunctive relief under §431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees, witness fees, and deposition expenses pursuant to §431.047(d) of the TFDCA.

13. **IT IS FURTHER ORDERED** that Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY DOUGLAS OSBORN shall be liable for payment in the amount of $200,000.00 as described in paragraphs 10, 11, and 12 above, such payment to be made in the following manner:

A. Within ten (10) days of the date of entry of this Final Judgment and Agreed Permanent Injunction, Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY DOUGLAS OSBORN shall pay $5,555.56 in the form of a certified or cashier's check made payable to the Office of the Attorney General as the first of 36 payments as described below.

B. Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY DOUGLAS OSBORN shall pay an additional $5,555.56 a month on the 5th day

of each month beginning in January, 2013 (except if that date is a holiday, the payment is due on the first business day thereafter) for the next 34 months and the 36th payment in the amount of $5,555.40, all in the form of a certified or cashier's check made payable to the Office of the Attorney General and mailed to the signatory attorney at the Attorney General of Texas, Consumer Protection and Public Health Division, 1410 Main Street, Suite 810, Dallas, Texas, 75202, referencing AG# 072465023.

Time is of the essence for the payment specified above. If the payment is not received by the State by the due date, the State will send a notice to Defendant GARY DOUGLAS OSBORN, through its attorney of record, and give Defendants, an additional ten (10) business days to pay, before declaring the full amount in paragraphs 10, 11, and 12 above immediately due and payable, less any payments already made. There is no penalty for pre-payment and if more than the required monthly amount is paid, the remaining payments will be recalculated based upon the number of remaining months.

13. **IT IS FURTHER ORDERED THAT** Defendants' agreement to and the Court's approval of this Judgment is expressly premised upon the above stipulations, as relied upon by the State of Texas in negotiating and agreeing to the terms of this Judgment.

VI. MISCELLANEOUS

14. If subsequent to the date of the signing of this Judgment by the Court, the State enacts new legislation with respect to compounding that is less rigorous than any injunctive terms of this Judgment and any Defendant wants to comply with the newly enacted legislation,

Defendant shall notify the Assistant Attorney General signing below of the same. If the Texas Attorney General agrees, he/she shall consent to a modification of such provision of the Judgment to the extent necessary. If the Attorney General disagrees and the parties are not able to resolve the disagreement, Defendant shall seek a modification from this court and will comply with the terms of the judgment until a court has made a determination otherwise.

15. **IT IS FURTHER ORDERED THAT** the clerk of the Court is authorized to issue such writs of execution or other process necessary to collect and enforce this Judgment.

16. **IT IS FURTHER ORDERED THAT** Defendants, by the signature of their authorized representatives below, hereby acknowledge notice of this permanent injunction and acceptance thereof; therefore, no writ need be issued.

17. **IT IS FURTHER ORDERED THAT** Defendants shall pay the filing fee to the court and all other costs, except as ordered herein, shall be paid by the party incurring them.

18. **IT IS FURTHER ORDERED THAT** this Court retains jurisdiction to enforce this Judgment.

19. **IT IS FURTHER ORDERED THAT** any and all payments made pursuant to this Judgment shall be made by cashier's check or money order, made payable to the STATE OF TEXAS, and mailed to the Attorney General of Texas' Consumer Protection and Public Health Division, 1410 Main Street, Suite 810, Dallas, Texas, 75202, referencing AG NO. 072465024.

20. It is further ordered, agreed and understood that this Judgment shall in no way affect the rights of individual citizens.

21. It is further ordered, adjudged, and decreed that Defendants shall not represent to

the public that this Judgment constitutes approval by Plaintiff or this Court of any of Defendants' actions or business activities.

22. It is further ordered, agreed and understood all other relief not expressly granted herein is denied.

SIGNED on _____, 2012.

_____
Presiding Judge

APPROVED AS TO SUBSTANCE AND FORM:

PLAINTIFF:

GREG ABBOTT
Attorney General of Texas

DANIEL T. HODGE
First Assistant Attorney General

JOHN SCOTT
Deputy Attorney General for Civil Litigation

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_____

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ATTORNEYS FOR PLAINTIFF

DEFENDANTS:

APOTHECURE, INC.

_____

RAYMOND J. BERTRAND, President

SPECTRA PHARM, INC.

_____

GARY D. OSBORN, President

_____

GARY D. OSBORN, individually

APPROVED AS TO FORM:

_____

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